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Colleen Coyne
Printed name of person mailing correspondence

Colleen Coyne
Signature of person mailing correspondence

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Christoph Hüls et al.	Art Unit:
Serial No.:	09/674,067	Examiner:
Filed:	October 25, 2000	
Title:	HUMAN DEADENYLATING NUCLEASE, ITS PRODUCTION AND ITS USE	

Assistant Commissioner for Patents and Trademarks
Washington, D.C. 20231

SUBMISSION OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

Applicants submit herewith the International Preliminary Examination Report corresponding to the above-referenced application. Applicants petition for any necessary extensions of time for submission of this document. In addition, if there are any charges, or any credits, please apply them to Deposit Account No. 03-2095.

Respectfully submitted,

Date: 2 January 2001

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Translation

PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 1998/F049 PCT	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/EP99/03071	International filing date (*day/month/year*) 05 May 1999 (05.05.99)	Priority date (*day/month/year*) 08 May 1998 (08.05.98)
International Patent Classification (IPC) or national classification and IPC C12N 15/55, 9/22, C12P 21/02, A61K 38/46, 39/395, 48/00, C12Q 1/34, 1/68		
Applicant AVENTIS RESEARCH & TECHNOLOGIES GMBH & CO. KG		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 5 sheets, including this cover sheet.

☒ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 1 sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☐ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 19 November 1999 (19.11.99)	Date of completion of this report 04 October 2000 (04.10.2000)
Name and mailing address of the IPEA/EP Facsimile No.	Authorized officer Telephone No.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/EP99/03071

I. Basis of the report

1. This report has been drawn on the basis of (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

☐ the international application as originally filed.

☒ the description, pages 1-25, as originally filed,
pages ______, filed with the demand,
pages ______, filed with the letter of ______,
pages ______, filed with the letter of ______.

☒ the claims, Nos. 1-14, as originally filed,
Nos. ______, as amended under Article 19,
Nos. ______, filed with the demand,
Nos. 15-18, filed with the letter of 27 September 2000 (27.09.2000),
Nos. ______, filed with the letter of ______.

☒ the drawings, sheets/fig 1-4, as originally filed,
sheets/fig ______, filed with the demand,
sheets/fig ______, filed with the letter of ______,
sheets/fig ______, filed with the letter of ______.

2. The amendments have resulted in the cancellation of:

☐ the description, pages ______
☐ the claims, Nos. ______
☐ the drawings, sheets/fig ______

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

4. Additional observations, if necessary:

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/EP 99/03071

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	7-18	YES
	Claims	1-2, 5-6	NO
Inventive step (IS)	Claims	3-4	YES
	Claims	7-18	NO
Industrial applicability (IA)	Claims	1-18	YES
	Claims		NO

2. Citations and explanations

Relevant documents:

D1: DATABASE DDBJ/EMBL/GENBANK [Online] Accession number AA447167.1, 5 June 1997 (1997-06-05), HILLIER, L. ET AL.: 'Soares total fetus Nb2HF8 9w homo sapiens cDNA clone 783875 5' (EST)' XP002121378

Novelty (PCT Article 33(2)):

1). In view of document D1 cited in the international search report, the subject matter of Claims 1-2 and 5-6 lacks the requisite novelty, since D1 already describes a nucleic acid which, over a range of 383 bp, is 100% identical with the claimed nucleic acid. This DNA is present as a cDNA clone, that is in a vector construct, and was isolated from a gene bank using a probe. In order to overcome this objection, it is suggested that the application be restricted to the subject matter of Claim 3. In this respect, the applicants are informed that the function (deadenylating nuclease) is an inherent feature of the nucleic acid already described in D1. Adding this inherent feature does not render novel

the subject matter of the application in its current broad form. In addition, Claim 1 lays claim to parts of a nucleic acid having at least 8 nucleotides. It is extremely doubtful whether such short nucleotide sequences code at all for a peptide with any function.

Inventive step (PCT Article 33(3)):

1.) Although the subject matter of Claims 7-18 is novel, it lacks the requisite inventive step. The use of a known nucleic acid (cf. D1) for producing a polypeptide with the help of a suitable vector and a suitable host cell is merely a routine method which does not require an inventive step. The same applies to a method for producing antibodies directed against such a routinely produced polypeptide and to the use of the known nucleic acid or the polypeptide or antibody obtained therewith for producing a drug (for treating cancer), for a diagnostic agent (for diagnosing cancer) or for a test for identifying functional interactions. The use of the nucleic acid already known from D1 for finding variants of human DAN or the use of the routinely produced polypeptide for the poly(A)-specific separation of nucleic acids also appears to be extremely obvious.

2). In view of the result of the international search report, the subject matter of Claims 3-4 is novel. The subject matter of said claims also involves the requisite inventive step. The cited prior art neither discloses nor suggests the production of a new human deadenylating nuclease using the specific nucleic acid sequence described in SEQ. ID NO. 12,

or the pharmaceutical uses thereof as per Claims 11-18.